

Notice of Allowability**Application No.**

09/654,688

Applicant(s)

OLSON ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the paper filed April 5, 2004.
2. ☒ The allowed claim(s) is/are 10-16.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date Nov. 30, 2000
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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Applicant's election without traverse of all inventions in the reply filed on April 5, 2004 is acknowledged.

It is noted that Applicants response to the restriction is non-compliant because no election of a specific invention was made. However, upon search both inventions were examined, and therefore the following allowance is in order.

Examiner's Amendments to the Specification:

Please replace Amendment A1 at page 1 with:

---Reference to Related Applications

This application is a continuation of U.S. Application Serial Number 09/051,872, filed April 22, 1998, now U.S. Patent 6,114,505, which is a 371 of PCT/US96/16934, filed October 23, 1996, which claims benefit to U.S. Provisional Application 60/006,020, filed October 23, 1995. ---

Please add the following abstract (taken from PCT/US96/16934):

---Abstract

The present invention relates to methods of reducing heme loss in hemoglobins to produce stability and improve expression yield of hemoglobins, particularly recombinant hemoglobins. Such methods are accomplished by introducing mutations in the alpha or beta subunits of hemoglobins to increase heme affinity. The present invention further relates to novel mutations that reduce such heme loss. ---

This abstract is also presented on a single page attached to this notice of allowance.

The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest reducing excess heme by administering alpha or beta globin having mutations that stabilize heme binding. The closest prior art appears to be Olson et al. (USP 6,022,849). In Olson et al. many of the mutations set forth in the current claims are taught.

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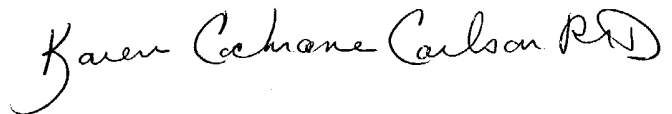
However, at col. 11, Olson et al. state that these mutated hemoglobins can be used as blood substitutes and Olson et al. do not teach or suggest to use these mutated hemoglobins to reduce heme, or be heme scavengers. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is (703) 308-0034. The Examiner can normally be reached daily except alternate Fridays from 7:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2329. The OFFICIAL fax phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script that reads "Karen Cochrane Carlson Ph.D.".

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

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Abstract

The present invention relates to methods of reducing heme loss in hemoglobins to produce stability and improve expression yield of hemoglobins, particularly recombinant hemoglobins. Such methods are accomplished by introducing mutations in the alpha or beta subunits of hemoglobins to increase heme affinity. The present invention further relates to novel mutations that reduce such heme loss.